

GENERAL DESCRIPTION

Process NPD st Sterile One-Step Germicidal Detergent is a sterile, gamma irradiated quaternary disinfectant designed for use in pharmaceutical facilities, and in areas where sterile products are required. Process NPD st detergent is a phosphate-free one-step cleaner, disinfectant, liquid concentrate consisting of four quaternary ammonium compound chains formulated with a compatible detergent system.

Process NPD st detergent is an effective one-step cleaner when diluted 1/2 oz/gal (0.4% v/v) with soft water or hard water to 400 ppm hardness (Association of Analytical Communities [AOAC] hard water) and in the presence of 5% blood serum.

Process NPD st detergent is intended for use on washable hard, non-porous environmental surfaces such as floors, walls, counters, tools, carts, and other equipment in pharmaceutical facilities. Process NPD st detergent does not contain any dye or perfume that could interfere with critical research studies or manufacturing processes. Process NPD st detergent may be used in fogging applications as an adjunct to regular cleaning and disinfecting.

The use-dilution of Process NPD st detergent can be used for cleaning and disinfecting glass, chrome, galvanized metal, stainless steel, porcelain, tile, washable painted or varnished surfaces, concrete, plastics, as well as resilient vinyl, linoleum, rubber, or terrazzo and other combination type floors.

FEATURES

BENEFITS

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| Double-bagged package | Facilitates handling in aseptic areas |
| Gamma irradiated to a minimum of 2.5 Mrd (25 kGy) | Validated to verify sterility |
| Available in a convenient unit dose package | Saves labor and time when used in a validated disinfection process |
| No dyes or perfumes | Fewer undesirable additives |

PHYSICAL PROPERTIES

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|-------------------------------------|-----------------------------------|
| Form..... | Colorless to light yellow or pink |
| Specific gravity (25°C [77°F])..... | 1.03 typical |
| pH (undiluted)..... | 10.2 typical |
| pH (0.4% v/v)..... | 10.7 typical |

GERMICIDAL PROPERTIES

The official test for determining the germicidal efficacy of a one-step cleaner disinfectant is the Use Dilution Method as stated in the AOAC Methods of Analysis. Process NPD st detergent diluted 1/2 oz/gal (0.4% v/v) in 400 ppm (as CaCO₃) hard water is effective against the following microorganisms in the presence of 5% blood serum, in 10 minutes at 20°C (68°F).

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| <i>Acinetobacter calcoaceticus</i> | ATCC 19606 |
| <i>Bordetella avium</i> | ATCC 35086 |
| <i>Bordetella bronchiseptica</i> | ATCC 10580 |
| <i>Campylobacter jejuni</i> | ATCC 29428 |
| <i>Candida albicans</i> , Clinical Isolate | N/A |
| <i>Candida parapsilosis</i> , Clinical Isolate | N/A |
| <i>Citrobacter freundii</i> | ATCC 8090 |
| <i>Enterobacter aerogenes</i> | ATCC 13048 |
| <i>Escherichia coli</i> | ATCC 25922 |

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|---|------------|
| <i>Klebsiella pneumoniae</i> | ATCC 13883 |
| <i>Listeria monocytogenes</i> | ATCC 19111 |
| <i>Mycoplasma gallisepticum</i> | ATCC 19610 |
| <i>Pasteurella multocida</i> | ATCC 29977 |
| <i>Proteus vulgaris</i> | ATCC 13315 |
| <i>Pseudomonas aeruginosa</i> | ATCC 9027 |
| <i>Pseudomonas cepacia</i> | ATCC 25609 |
| <i>Salmonella choleraesuis</i> | ATCC10708 |
| <i>Salmonella enteritidis</i> | ATCC 13076 |
| <i>Salmonella typhimurium</i> | ATCC 14028 |
| <i>Serratia marcescens</i> | ATCC 8100 |
| <i>Shigella flexneri</i> | ATCC 12022 |
| <i>Shigella sonnei</i> | ATCC 25931 |
| <i>Staphylococcus aureus</i> | ATCC 6538 |
| <i>Staphylococcus aureus</i> | ATCC 25923 |
| <i>Staphylococcus aureus</i> (MRSA), Multiply (<i>Methicillin</i>)-Resistant Clinical Isolate | N/A |
| <i>Staphylococcus epidermidis</i> | ATCC 12228 |
| <i>Streptococcus faecalis</i> | ATCC 19433 |
| <i>Streptococcus pyogenes</i> | ATCC 19615 |

Process NPD st detergent is effective in three minutes on hard surfaces against *P. aeruginosa*, ATCC 13388, according to the AOAC Use-Dilution Test when diluted with 400 ppm hard water to make a 1 oz/gal (0.8% v/v) solution, in the presence of 5% added organic soil (serum) at 20°C (68°F)

FUNGICIDAL PROPERTIES

The official test for determining the fungicidal efficacy of a one-step cleaner disinfectant is the Use-Dilution Method as described in the AOAC Methods of Analysis, and modified as required by Environmental Protection Agency (EPA) regulations. Process NPD st detergent concentrate diluted 1/2 oz/gal (0.4% v/v) in 400 ppm (as CaCO₃) hard water is effective against Trichophyton mentagrophytes in the presence of 5% blood serum, 10 minutes at 20°C (68°F)

VIRUCIDAL PROPERTIES

Process NPD st detergent is effective against the following viruses according to the EPA approved virucidal assay method when diluted with 300 ppm hard water to make a 1/2 oz/gal (0.4% v/v) solution, in the presence of 5% organic soil (serum) in 10 minutes at 20-25°C (68-77°F) on hard non-porous environmental surfaces:

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|---|-------------|
| <i>Canine distemper</i> | ATCC-128 |
| <i>Canine parainfluenza</i> | ATCC VR-399 |
| <i>Chlamydia psittici</i> (<i>Feline Pneumonitis</i>) | N/A |
| <i>Feline rhinotracheitis</i> | ATCC VR-636 |
| * <i>Herpes simplex Types 1 and 2</i> | N/A |
| <i>Infectious bronchitis</i> | ATCC VR-22 |
| <i>Infectious laryngotracheitis</i> | ATCC VR-783 |
| * <i>Influenza A₂</i> (Japan-305) | N/A |

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|--------------------------|--------------|
| <i>Marek's Disease</i> | ATCC VR-2002 |
| * <i>Mouse hepatitis</i> | ATCC VR-764 |
| <i>Newcastle Disease</i> | ATCC VR-109 |
| * <i>Vaccinia Virus</i> | N/A |

* 400 ppm Hard Water

When tested by an EPA approved dilution method, a dried film of HIV-1 (AIDS) virus, with added 5% organic soil (serum) was completely inactivated by 1/2 oz/gal (0.4% v/v) solution of Process NPD st detergent in 400 ppm AOAC hard water in 30 seconds at 20°C (68°F). Although efficacy at a 30 second contact time has been shown to be adequate for HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for all organisms. Process NPD st detergent is effective against *Canine parvovirus*, ATCC VR-953, *Feline calcivirus*, ATCC VR-120, and Infectious Bursel Disease (Lukart Strain) according to the EPA approved virucidal assay method when diluted 2 oz/gal (1.6% v/v) in 400 ppm hard water in 5% organic soil (serum) in 10 minutes at 20-25°C (68-77°F) on hard, non-porous environmental surfaces.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cleaning and Disinfecting

Add 1 oz (29.1 mL) to 2 gal of water used. Always add this product to premeasured water. Gently mix for a uniform solution. Apply solution with a cloth, sponge, mop, brush or coarse spray using normal cleaning methods. Thoroughly wet all surfaces to be cleaned. Allow treated surfaces to soak for 10 minutes, then remove excess solution with a wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution when it becomes dirty and replace with a fresh solution. A properly prepared solution with deionized water of Process NPD st detergent intended for use as a hard surface disinfectant has a shelf life of 7 days (use life) when stored in a closed container such as a spray bottle. This is a complete product. Do not add other chemicals. Use only as directed.

Cleaning and Disinfecting Food Preparation, Processing Facilities and Equipment

Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (1/2 oz/gal, prepared as directed above). Scrub to loosen all soils. Allow to soak for 10 minutes, and then pick up excess solution with a wrung-out applicator. Thoroughly rinse all wetted and cleaned food contact surfaces with potable water.

Animal Husbandry, Animal Research, and Poultry Facility Cleaning and Disinfecting

Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter and manure from the floors, walls and surfaces of facilities transversed or occupied by animals. Empty all troughs, racks and other feeding and watering appliance. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of 1/2 oz. per gallon water (1:256 dilution). Apply solution with a cloth, sponge, mop, brush, coarse spray using normal cleaning methods or by fogging following cleaning. Allow surfaces to remain wet for 10 minutes. (For fogging, fog the desired area at 32 to 64 oz of use dilution per 1000 cubic feet using equipment with an automatic timer. Do not remain in treated areas; allow at least two hours after fogging is complete before reentering fogged area. Before fogging remove or cover any food or packaging material with waterproof coverings.) Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, vehicles and other closed spaces. Do not house livestock or empty equipment until treatment has absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders and waterers with soap or detergent and rinse with potable water before reuse.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage

Store in a secure area away from flammable materials. If frozen, thaw and remix before use.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and Local authorities, or by burning. If burned, stay out of smoke.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

PRECAUTIONS

Information concerning human and environmental exposure may be reviewed on the Material Safety Data Sheet (MSDS) for the product. For additional information regarding incidents involving human and environmental exposure, call 314-535-1395.

For further information, please contact:



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